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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,038	01/09/2004	Avram Reuben Gold	2111-040037	7887
28289	7590	11/29/2005		
THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219			EXAMINER LEWIS, AARON J	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/755,038

Applicant(s)

GOLD, AVRAM REUBEN

Examiner

AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,13,14 and 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-12 and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of the restriction between claims 1-20 and claims 21-28 in combination with an election of species within claims 1-20 and 21-28, respectively in the reply filed on 09/19/2005 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner to search the subject matter of all claims 1-28. This is not found persuasive because the method of treating a patient suffering from a functional somatic syndrome differs from merely diagnosing the illness in a patient. A physician typically employs a wide range of diagnostic tools in combination to differentiate a particular illness from another. Subsequent to a diagnosis a physician typically plots a treatment regimen based upon patient specific variables and severity of illness. Claims 1-20 define a method of treating a patient having a particular illness whereas claims 21-28 define a method of diagnosing an illness in a patient. Moreover, claims 1-20 define two patentably distinct methods of treating a patient suffering from a functional somatic syndrome: stabilizing a patient's airway with positive pressure (i.e. claims 4,5,15,16) and stabilizing a patient's airway with an oral appliance (i.e. claims 2,3,13,14). A proper search for these two separate and distinct methods of stabilizing a patient's airway would not typically overlap and to search both would require searching for two separate and distinct ways of stabilizing a patient's airway.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1,4-9,11,12,15-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kowallik et al. ('766).

As to claim 1, Kowallik et al. disclose a method of treating functional somatic syndromes comprising the steps of: identifying a patient as having a functional somatic syndrome (e.g. daytime sleepiness, negative effects on the cardiovascular system discussed at col.1, lines 33 and lines 39-42); and treating such a patient with an airway stabilization technique (col.7, line 56-col.8, line 2).

As to claims 4,15, Kowallik et al. disclose treating such a patient with an airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy (#20-24 and col.7, line 56-col.8, line 2).

As to claims 5,16, Kowallik et al. disclose CPAP as the positive airway pressure therapy is selected from the group consisting of: continuous positive airway pressure, bi-level positive airway pressure, and auto-titrating positive airway pressure (#20-24 and col.7, line 56-col.8, line 2).

As to claims 6,17, Kowallik et al. disclose identifying a patient as having a functional somatic syndrome includes identifying a symptom of the functional somatic syndrome, wherein the symptom is selected from the group consisting of: chronic fatigue, irritable bowel, migraine headaches, tension headaches, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia (i.e. micro-arousals discussed at col.1, lines 39-42), sleep maintenance insomnia, unrefreshing sleep (i.e. daytime sleepiness discussed at col.1, line 33), EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, depression, orthostatic syncope, alpha-delta sleep.

As to claims 7,18, Kowallik et al. disclose monitoring such a patient for an inspiratory airflow limitation (col.4, lines 51-67 and fig.3) during sleep.

As to claims 8,19, Kowallik et al. (col.8, lines 7-11) disclose further comprising the step of categorizing a patient who has an inspiratory airflow during sleep of approximately fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient.

As to claims 9,20, Kowallik et al. (col.6, lines 10-62) disclose categorizing a patient who has an inspiratory airflow during sleep of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient.

As to claim 11, Kowallik et al. disclose the functional somatic syndrome is selected from the group consisting of: chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, Gulf War syndrome, premenstrual syndrome, sleep-onset insomnia (i.e. micro-arousals discussed at col.1, lines 39-42), sleep maintenance insomnia, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, chronic whiplash, and restless leg/periodic limb movement syndrome.

Claim 12 is substantially equivalent in scope to claim 1 and is anticipated by Kowallik et al. for the reasons discussed above with respect to claim 1.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kowallik et al. ('766) in view of Bennett ('686).

The difference between Kowallik et al. and claim 10 is observing alpha-delta sleep of such a patient to diagnose the functional somatic syndrome.

Bennett (col.1, lines 38-51) teaches observing alpha-delta sleep of such a patient to diagnose the functional somatic syndrome fibromyalgia.

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It would have been obvious to modify Kowallik et al. to include monitoring patients for alpha-delta sleep to diagnose a functional somatic syndrome as taught by Bennett because Kowallik et al. (col.3, lines 44-51 and col.8, lines 12-14) the use of sleep monitoring devices including detecting sleep stages for use in diagnosing functional somatic syndromes such as UAR, hypopnea and OSA.

### ***Conclusion***

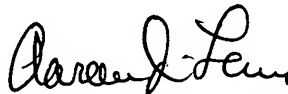
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant methods of treating functional somatic syndromes including UAR, hypopnea and OSA.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
November 21, 2005